

**REMARKS****I. Claim Amendments**

The claims have been amended to clarify that the dosage form of claim 1, and the claims dependent either directly or indirectly thereon, comprise a combination of active agents, wherein the combination consists of (1) a H<sup>+</sup>,K<sup>+</sup>-ATPase inhibitor, and (2) a gastric antisecretory prostaglandin.

Claim 40 has been amended to clarify that the dosage form of claim 40 comprises a combination of active agents, wherein the combination consists of (1) a H<sup>+</sup>,K<sup>+</sup>-ATPase inhibitor, (2) a gastric antisecretory prostaglandin and (3) a calcium channel blocker.

Thus, as amended, the claimed invention excludes unspecified active agents, e.g., NSAIDs. Support is provided by the specification as originally filed. For example, the disclosure at page 7, lines 10-16, contemplates the embodiments of claims 1 and 40.

Applicants submit that no new matter has been introduced by any of the claim amendments.

**II. Claim Rejections – 35 U.S.C. §112**

Claims 4, 6-11, 14-18, 22-27, 31, 32, 38 and 39 are rejected as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicants submit that the amended claims overcome the rejections. Specifically, the dosage form of amended claim 1 is defined by the open-ended transitory expression “comprising”. It is only the recited combination of active agents that is defined by the closed-ended transitory expression “consisting”.

Withdrawal of the §112 rejection is requested.

### III. Claim Rejections – 35 U.S.C. §103

Claims 1-4, 11-27, 35, 38 and 39 are rejected under 35 U.S.C. §103(a) for alleged obviousness in view of US 6,365,184 to Depui et al. (“Depui”) in combination with US 6,387,410 to Woolfe et al. (“Woolfe”).

Depui discloses and claims a combination therapy including a proton pump inhibitor and a NSAID. Woolfe discloses a mixture of a NSAID and a prostaglandin to treat any side-effects associated with the administration of the NSAID. The Examiner alleges that it would have been obvious, at the time the claimed invention was made, to combine Depui with Woolfe to arrive at the claimed invention.

Independent claim 1 has been amended to define the claimed dosage form as comprising a combination of active agents, wherein the combination of active agents consists of a proton pump inhibitor and a prostaglandin. Similarly, claim 40 has been amended to define the claimed dosage form as comprising a combination of active agents, wherein the combination of active agents consists of a proton pump inhibitor, prostaglandin and a calcium channel blocking agent.

Thus, as amended, the claimed invention of claims 1 and 40 excludes unspecified active agents, e.g., NSAIDs. In contrast, the combination of Depui and Woolfe results in a dosage form characterized by a combination of a proton pump inhibitor and a NSAID. Therefore, the claimed dosage form is both novel and nonobvious in view of the cited combination of references. The combination of Depui and Woolfe does not suggest the claimed invention which excludes unspecified active agents such as NSAIDs. Nor would the combination of Depui and Woolfe produce the claimed invention.

Furthermore, contrary to the Examiner’s allegation, the specification does not disclose or suggest that the claimed dosage forms may also include a NSAID. Rather, the disclosure appearing at page 20, lines 19-21, describes an optional therapy including the administration of

the claimed dosage form "*in combination with other dosage forms*" comprising a calcium channel blocking agent, an NSAID or other antiulcerative agents. Thus, by the expression "other dosage forms", the only reasonable interpretation of the disclosure at page 20, lines 19-21, is the *separate administration* of the claimed dosage form and a second dosage form comprising a calcium channel blocking agent, an NSAID or other antiulcerative agent. This point is correctly stated in the Interview Summary (Paper No. 16), mailed September 4, 2003.

For all of the foregoing reasons, withdrawal of the §103 rejection based on the combination of Depui and Woolfe is requested.

#### **IV. Claim Rejections – 35 U.S.C. §103**

Claims 1-4, 11-27, 35, 38 and 39 are rejected under 35 U.S.C. §103(a) for alleged obviousness in view of Akira Tari et al. ("Digestive Diseases and Sciences, Vol. 42") ("Tari") in combination with Depui. Tari does not disclose an oral dosage form of the combination omeprazole-cnprostil. Accordingly, the Examiner relies on Depui for a disclosure of an oral dosage form comprising a proton pump inhibitor and a NSAID. For the reasons set forth in Section IV, above, the combination of Tari and Depui does not suggest the claimed invention which excludes additional unspecified active agents such as NSAIDs which are required by Depui.

Withdrawal of the §103 rejection is requested.

#### **V. Claim Rejections – 35 U.S.C. §103**

In the final Office Action, claims 1-4, 6-27, 31, 32, 35 and 38-40 are rejected under 35 U.S.C. §103(a) for alleged obviousness in view of the combination of Depui, Woolfe and US

5,582,837 to Shell ("Shell"). Shell is relied upon for its alleged disclosure of a dosage form containing a calcium channel blocker for the treatment of gastric diseases.

As noted by the Examiner, the expected result would be a single dosage form comprising a combination of a proton pump inhibitor, NSAID, calcium channel blocker and prostaglandin. However, the claimed invention as defined by the independent claims 1 and 40 excludes a NSAID. Therefore, the combination of Depui, Wolfe and Shell does not suggest the claimed invention.

Withdrawal of the §103 rejection is requested.

**CONCLUSION**

Applicants respectfully submit that the claims are in condition for allowance, which action is earnestly solicited.

Authorization is hereby given to charge any additional fee required in connection with the communication to Deposit Account No. 23-1703.

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Respectfully submitted,

  
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